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The type of SARS-CoV-2 vaccine does not affect ovarian function in assisted reproduction cycle

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Objective: To assess whether vaccination or the type of vaccine against SARS-CoV-2 affects ovarian function in an assisted reproduction treatment.

Design: A retrospective and observational study.

Setting: University-affiliated private in vitro fertilization (IVF) center.

Patient(s): Five hundred one patients who had received the complete vaccination schedule.

Intervention(s): Treatment before and after vaccination.

Main Outcome Measure(s): Parameters for both reproductive outcomes and IVF results in patients vaccinated

Result(s): We included 510 patients, distributed as follows: 13.5% (n = 69) received a viral vector vaccine, either the adenovirus serotype 26 vector vaccine (Ad26.CoV2.S; Janssen; n = 31) or the chimpanzee adenovirus vector vaccine (ChAdOx; AstraZeneca; n = 38). The remaining 86.5% (n = 441) received an messenger RNA vaccine from either Pfizer-BioNTech (n = 336) or Moderna (n = 105). Sample size for the unexposed women was n = 1190. No differences were found in any of the evaluated parameters for both reproductive outcomes and IVF results in patients vaccinated with any adenovirus or messenger RNA vaccine. When we compared the results after vaccination with different types of vaccines between the exposed and unexposed groups, and similar results were obtained in the days of stimulation or the doses of administered follicle stimulating hormone. Finally, the numbers of oocytes were as follows: Johnson & Johnson (9.2 ± 2.6), AstraZeneca (7.7 ± 1.2), Moderna (11.3 ± 1.8), Pfizer (12.6 ± 1.0), and the unvaccinated group (10.2 ± 1.5), $P=0.057$.

Conclusion(s): These early results suggest no measurable detrimental effect on reproductive outcomes, regardless of the type of vaccine received. (Fertil Steril® 2023;119:618-23. ©2022 by American Society for Reproductive Medicine.)

El resumen está disponible en Español al final del artículo.

Key Words: SARS-CoV-2, ovarian function, mRNA vaccine, adenovirus vaccine

Since the pandemic broke out over 2 years ago, the quest for a vaccine became a matter of top priority. The time needed to develop this vaccine was shorter than that historically spent on other vaccines and/or medications (1); however, everyone expected this objective to be achieved, with high investment, biotechnological advances, and logistics as the main drivers of the developmental process.

Currently in Spain, 4 types of vaccines have been administered: Pfizer/

BioNTech (BNT162b2), Moderna (messenger [RNA] -1273), AstraZeneca (ChAdOx), and Janssen Pharmaceuticals (Ad26.COVS2.S). Pfizer and Moderna vaccines are mRNA-based vaccines that do not contain live viral particles. In terms of vaccine development, the implementation of this new technology is completely innovative, as it borrows the cell's translation machinery to produce enough spike protein to generate an immunogenic response. On the other hand, the

AstraZeneca and Janssen vaccines are based on the action of adenoviruses, which do not have replicative activity and can stimulate the immune response without the presence of adjuvants (2). The global aim of these vaccines is the induction of antibodies and T cells, targeting the SARS-CoV-2 spike protein.

Women of reproductive age have characteristics which often exclude them from clinical trials. This has given rise to many unanswered questions about the safety of vaccines for fertility, especially those based on mRNA (3). Vaccine hesitancy has been a serious problem in eradicating the disease. This reluctance has been exacerbated by social media, which has instilled fear and uncertainty toward vaccination in large portions of the population. The impact of the vaccine on fertility is the subject of numerous

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rumors and much contradictory information. These concerns have spread to pregnant women; despite an endorsement from official and professional bodies unequivocally recommending Covid-19 vaccination, vaccine hesitancy remains high (4).

Both the rapid spread of the disease and the inadequacy of vaccination campaigns may be related to concerns about the possible detrimental effects on future fertility. Currently, specialists advising their patients face a lack of real-world data regarding the impact of vaccination on the success rates of assisted reproductive procedures (5). Although possibility has been raised that the infection could affect fertility, no study has provided solid evidence on a direct gonadal effect of either the disease or the vaccine.

The objective of our study was to evaluate the results of an assisted reproduction treatment before and after receiving the SARS-CoV-2 vaccine.

MATERIALS AND METHODS

This was a retrospective and observational study conducted from January 2021 to October 2021 in women vaccinated against SARS-CoV-2 who underwent assisted reproductive treatment before and after vaccination at any of the 14 clinics belonging to the Instituto Valenciano de Infertilidad Reproductive Medicine Associates of New Jersey group in Spain. The unvaccinated status group included patients receiving a treatment during the same study period but who had not yet been vaccinated. Institutional Review Board approval (2109-MAD-084-AR) was obtained; informed consent was not necessary because the study was based on nonidentifiable records, as approved by the Ethics Committee. The study complied with the Spanish law governing assisted reproductive treatments (14/2006).

The medical records of the patients who had received the complete vaccination schedule were retrospectively reviewed to identify before and after vaccination treatments. Data were obtained from our clinical database (SIVIS, IVI Digital Information Management Platform). The second dose of the vaccine was administered as recommended.

To minimize bias, each woman acted as a self-control before and after vaccination. Severe male factor was excluded from the analyzed database as this condition is an indication for preimplantation genetic diagnosis, and our study population does not include patients with this treatment. All women, including those who had received the complete vaccination schedule, regardless of the type of vaccine administered (mRNA or viral vector), and those belonging to the unexposed group, underwent the same ovarian stimulation protocol. In all cases, the assisted reproduction treatments were performed with their own oocytes.

We performed 2 complementary analyses to establish the effect, if any, of SARS-CoV-2 vaccination on ovarian function. First, we established a before and after exposure comparison to evaluate the possible effects of the vaccines on different reproductive outcomes. Second, we compared the results in vaccinated women who had undergone reproductive treatment after vaccination with those of unvaccinated women who had also undergone this type of treatment.

Outcomes between pre- and post-vaccination treatment were compared. Primary outcome was the number of retrieved

oocytes; as secondary outcomes variables such as the total dose of gonadotropins, the length of stimulation, or the fertilization rate were included.

As this was a retrospective study, we calculated the statistical power of our predefined sample size through a post hoc power analysis. Given the analytical nature of the study and the estimation of the sample size, the valued statistical power of 100%. IVF treatment parameters are presented as mean \pm standard deviations or percentage. Comparisons between before and after vaccination values were conducted with paired t-tests and $P \leq .05$ was considered statistically significant. The significance of fertilization rate was assessed by McNemer's test. A linear regression was conducted to quantify the effect of age and status vaccination (before vaccination and after vaccination) on the number of retrieved oocytes. Statistical analysis was performed with the Statistical Package for Social Sciences 23 (SPSS; Chicago, IL, UDSA).

RESULTS

We included 510 patients, distributed as follows: 13.5% ($n = 69$) received a viral vector vaccine, either the adenovirus serotype 26 vector vaccine (Ad26.CoV2.S; Janssen; $n = 31$) or the chimpanzee adenovirus vector vaccine (ChAdOx; AstraZeneca; $n = 38$). The remaining 86.5% ($n = 441$) received an mRNA vaccine from either Pfizer-BioNTech ($n = 336$) or Moderna ($n = 105$). The sample size of the unexposed women was $n = 1190$. None of the couples had any known underlying diseases, and the interval between the time of the second vaccination and the date of the after vaccination treatment was approximately 2 months.

Patient's clinical characteristics and the details of their IVF cycle attempts before and after receiving an adenovirus vector vaccine (Janssen or Astrazeneca) are shown in Table 1. Our results showed no differences in the reproductive outcomes and IVF cycle results for any of the evaluated variables, i.e., there was no change in the length of ovarian stimulation (10.7 [1.8] \pm vs. 11.0 [1.7], $P = .0356$), the total dose of gonadotropin used (2300 [720] vs. 2140 [735], $P = .125$), or the number of retrieved oocytes (7.6 [4.8] vs. 8.0 [5.2], $P = .698$) between the before and after vaccination procedures, respectively.

The age difference of the patients between the first and the second cycle was approximately 1 year (36.8 [5.1] vs. 37.9 [5.0], $P = .356$).

Subsequently, we performed the same retrospective analysis but focused on patients who had been vaccinated with an mRNA vaccine (Pfizer or Moderna) (Table 2). In line with what was previously observed, we did not find relevant differences between the 2 procedures in any of the variables analyzed, including the length of ovarian stimulation (10.9 [2.1] vs. 11.2 [1.8], $P = .695$), the total dose of gonadotropin used (1980 [675] vs. 2000 [790], $P = .697$), or the number of retrieved oocytes (9.1 [6.6] vs. 8.3 [6.0], $P = .137$) between the before and after vaccination procedures, respectively. As in the previous analysis, the mean interval between oocyte retrievals was 1 year (33.7 [7.6] vs. 34.8 [7.7], $P = .156$). To confirm the true effect of the differences observed in the number of retrieved oocytes before and after vaccination, a post hoc analysis was performed to detect a mean difference of

TABLE 1**Ovarian stimulation and IVF results from women who received adenovirus vaccines.**

	Before vaccination (n = 69)	After vaccination (n = 69)	P value
Age (y)	36.8 (5.1)	37.9 (5.0)	.356
Body mass index (kg/m ²)	24.2 (3.5)	23.9 (3.8)	.759
Days of stimulation	10.7 (1.8)	11.0 (1.7)	.815
Estradiol_human chorionic gonadotropin	1905 (350)	1655 (240)	.510
P4 (progesterone)_human chorionic gonadotropin	0.8 (0.6)	0.6 (0.5)	.758
Antral follicle count	10.3 (5.1)	10.1 (6.5)	.847
Follicle stimulating hormone doses (IU)	2300 (720)	2140 (735)	.125
Human menopausal gonadotropin doses (IU)	1260 (805)	1610 (1030)	.369
Oocytes	7.6 (4.8)	8.0 (5.2)	.698
Metaphase II	5.5 (4.9)	5.4 (4.1)	.425
Fertilization rate (%)	71%	75%	.600
Usable blastocyst rate	41.3%	44.5%	.214

Requena. SARS-CoV-2 vaccines do not affect reproductive outcomes. Fertil Steril 2023.

2 oocytes; a power of 97% was obtained, meaning that the difference of 0.8 oocytes was not statistically significant with the mRNA vaccine

Lastly, to determine whether the type of vaccine received could affect the success of the treatments, we compared the cycles after vaccination for each type of vaccine with those of the women in the unvaccinated group (Table 3). Our results showed that women vaccinated with Janssen were on the average older (39.7 [6.7]) than those in the other groups, although no difference was observed ($P=.072$). The other groups' mean ages were as follows: AstraZeneca (36.8 [3.5]), Moderna (35.7 [6.7]), Pfizer (34.6 [7.9]), and the unvaccinated group (37.8 [4.1]). This did not affect other parameters such as the days of stimulation ($P=.336$), the doses of follicle stimulating hormone administered ($P=.392$), or the number of oocytes ($P=.057$), where no differences were recorded between the vaccinated and the unvaccinated group.

A Poisson regression model was performed to evaluate the effect of possible confounding factors on the number of oocytes retrieved. The variables included in the model are age, because of its recognized impact on the results of an assisted reproduction treatment; and vaccination status (before and after vaccination), as it is the condition assessed in this study. The results of this analysis indicate, as expected, that

age does notably influence the results of the cycle (-0.52 [-0.054 to -0.050], $P<.001$), whereas vaccination status is independent of the data obtained (-0.028 [-0.065 to 0.009], $P=0.143$). Lastly, when we compare the group of vaccinated women with those who were not vaccinated, it seems that the Janssen vaccine may present differences with respect to the rest of the study groups, we performed a new analysis with the parameter vaccinated and unvaccinated as exposure variables. The results were similar to those obtained in the previous analysis with age having a significant influence on the number of oocytes obtained (-0.68 [-0.053 to -0.083], $P<.001$), whereas vaccination status and/or the type of vaccine did not affect the results obtained, (-0.312 [-1.485 to 0.862], $P=.602$)

DISCUSSION

Our results suggest that neither vaccination nor the type of vaccine administered affects ovarian function or IVF results in assisted reproductive treatments.

For a long time, rumors have circulated about a link between SARS-CoV-2 vaccination and infertility. It is understandable that people are apprehensive, especially regarding a new vaccine. Ordinarily, most side effects can be ruled out

TABLE 2**Ovarian stimulation and in vitro fertilization results from women who received mRNA vaccines.**

	Before vaccination (n = 441)	After vaccination (n = 441)	P value
Age (y)	33.7 (7.6)	34.8 (7.7)	.156
Body mass index (kg/m ²)	23.9 (1.3)	23.2 (1.8)	.695
Days of stimulation	10.9 (2.1)	11.2 (2.0)	.561
Estradiol_human chorionic gonadotropin	2320 (1700)	2290 (1620)	.847
P4 (progesterone)_human chorionic gonadotropin	0.8 (0.9)	0.9 (0.8)	.903
Antral follicle count	16.0 (13.8)	15.4 (13.7)	.632
Follicle stimulating hormone doses (IU)	1980 (675)	2000 (790)	.697
Human menopausal gonadotropin doses (IU)	1275 (775)	1255 (800)	.863
Oocytes	9.1 (6.6)	8.3 (6.0)	.137
Metaphase II	7.4 (5.2)	7.2 (5.6)	.589
Fertilization rate (%)	79%	77%	.895
Usable blastocyst rate	40.7%	41.1%	.847

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TABLE 3

	AstraZeneca (n = 38)	Janssen (n = 31)	Moderna (n = 105)	Pfizer (n = 336)	Unvaccinated (n = 1190)	P value
Age (y)	36.8 (3.5)	39.7 (6.7)	35.7 (6.7)	34.6 (7.9)	37.8 (4.1)	.072
Body mass index (kg/m ²)	23.6 (4.1)	25.0 (2.4)	22.7 (3.5)	23.3 (3.8)	22.8 (3.3)	.516
Days of stimulation	11.1 (2.1)	10.6 (1.1)	11.3 (2.8)	11.1 (3.2)	11.1 (2.6)	.336
Estradiol_human chorionic gonadotropin	1793 (886)	1449 (1040)	2481 (900)	2250 (1540)	2218 (1250)	.376
P4 (progesterone)_human chorionic gonadotropin	0.8 (0.2)	0.4 (0.3)	0.75 (0.2)	0.8 (0.3)	0.8 (0.5)	.764
Antral follicle count	11.3 (7.3)	8.1 (4.2)	14.1 (10.1)	15.7 (12.1)	10.8 (9.3)	.202
Follicle stimulating hormone doses (IU)	2283 (810)	1810 (450)	2098 (790)	1980 (790)	1800 (610)	.392
Human menopausal gonadotropin doses (IU)	1521 (1090)	1792 (960)	1211 (670)	1264 (830)	1330 (900)	.229
Oocytes	9.2 (5.3)	7.7 (4.4)	9.8 (9.1)	8.8 (9.1)	10.2 (9.3)	.057
Metaphase II	6.7 (5.7)	5.8 (4.8)	8.3 (5.6)	7.2 (5.6)	8.5 (7.2)	.089
Fertilization rate (%)	80%	78%	70%	81%	75%	.340
Usable blastocyst rate	41.1%	45.5%	40.9%	42.0%	45.2%	.254

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during clinical trials, but the short timeframe of the development of the SARS-CoV-2 vaccine suggests it is difficult to exclude events that could potentially appear in the coming decades (6). In this context, the public's doubts are more focused on the relatively new technology involved in the development of mRNA vaccines. Regarding these misgivings, it is important to point out that the first trials conducted with these mRNA vaccines date back 15 years; therefore, the problems with these types of vaccines should have come to light by now. One of the unsubstantiated arguments for the mRNA vaccine negatively impacting fertility was the presumed similarity between the SARS-CoV-2 spike protein and syncytin-1, a protein that is critical to the formation of the placenta in a developing embryo (7). Antibodies produced against this protein could also attack the placenta and cause miscarriages; however, these claims have been reversed as the vaccine does not contain syncytin-1 or the mRNA sequence for it.

The current evidence regarding SARS-CoV-2 vaccine effects on human fertility is very limited. From our findings, the vaccine does not seem to affect women's fertility. Specifically, no relevant differences in outcomes were observed in the treatments that each patient underwent before and after vaccination. These data coincide with those of previously published studies (3, 5, 8–10) in which it is unanimously stated that vaccination does not lead to any detrimental effect on the female reproductive physiology. Additionally, using a frozen embryo model, there was no significant difference between implantation and sustained implantation rates in vaccinated women, those who had the infection and those who were still seronegative (7). Although a priori results obtained thus far suggest that the vaccines do not seem to influence ovarian function, we must be cautious because the sample size is small and there is variability in the number of cases included in each type of vaccine group.

This line of argument holds regardless of the vaccine received. As we have previously commented, adenovirus vaccines involve the stimulation of the immune system to attack the SARS-CoV-2 virus, whereas mRNA vaccines use the principle of inoculating RNA coding for the virus's spike protein, which on its expression in cells stimulates the immune system

to produce antibodies (11). Our results indicate that exposure to either type of vaccine might not affect ovarian reserve, ovarian stimulation characteristics, or folliculogenesis. Even if we focus on the time between oocyte retrievals, which was approximately 1 year, we might expect fertility to vary with increasing patient age (3); however, we did not find clinical and biological differences in this aspect either, as no decline was observed in the cycle after vaccination. We would like to specify that the assessment of ovarian function was performed in a population with intrinsic difficulty in conceiving, but it could represent a good starting point.

Ultimately, when we compare only the after vaccination cycles between the different types of vaccine and a similar population of unvaccinated women, the results maintain the same previous trend, although differences in the sample size between groups might be affecting these results. Despite the clear evidence of intimate follicular immune exposure, both after infection with SARS-CoV-2 and after vaccination, the steroidogenic machinery of the follicle did not show any measurable difference between the exposed and unexposed women (5). It is important to remember that the women vaccinated with the Janssen vaccine were on average older than the women in the other groups; this could explain a decreased ovarian reserve and worse results in terms of the number of retrieved oocytes, although in no case were these differences relevant. However, when we study the effect of age and vaccination status (before and after vaccination and vaccinated or unvaccinated) on the number of oocytes retrieved, we observe that age is a factor to consider on the results of the cycle. As we previously commented, women vaccinated with Janssen were older, and an increase in the sample size could show the differences observed in the vaccination profiles (12).

Regarding vaccination status, and supporting the hypothesis of this study, it does not seem to affect ovarian function during assisted reproduction treatment. These results are in line with what has been published so far for pregnant women, with many observational studies comparing the perinatal outcomes between vaccinated and unvaccinated pregnant women and provided reassuring findings; harmful effects on pregnancy or the newborn were not demonstrated

(4, 13, 14). Therefore, pregnant women should be prioritized for vaccination ahead of their nonpregnant peers of similar age. In fact, the latest published findings related to the impact of the vaccine on fertility reinforce the message that no adverse association between SARS-CoV-2 vaccination and fertility was observed (15). Based on the concern raised by changes in the menstrual cycle, it has been reported that vaccination might be associated with short-term changes toward increased menstrual cycle length but are independent of the type of vaccine administered (16, 17). In both cases, this information should be used to help make decisions about the SARS-CoV-2 vaccine among the population of women of reproductive age, and particularly among those who are trying to achieve a pregnancy now or in the future not too far.

This study had certain limitations, as it was an observational study and confounders cannot be excluded, more data are needed to draw firm conclusions. It is critical that the sample size be increased to ascertain that the results observed in this study hold true in the general population.

In summary, this work provides encouraging data showing that neither SARS-CoV-2 vaccination nor the type of vaccine is likely to affect fertility in women. Rumors and myths about the effects of SARS-CoV-2 vaccines have been widespread, but from a reproduction perspective, vaccines should be recommended because there is no theoretical risk that they cause infertility.

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El tipo de vacuna contra la SARS-CoV-2 no afecta a la función ovárica en los ciclos de reproducción asistida.

Objetivo: Evaluar si la vacunación o el tipo de vacuna utilizada contra la SARS-CoV-2 afecta a la función ovárica en tratamientos de reproducción asistida.

Diseño: Estudio retrospectivo y observacional.

Marco: Centro de fecundación in vitro (FIV) privado afiliado a una universidad.

Pacientes: 501 pacientes que habían recibido la pauta completa de vacunación.

Intervenciones: Tratamiento antes y después de la vacunación.

Medida principal de resultado: Parámetros tanto de resultados reproductivos como resultados de FIV en pacientes vacunadas.

Resultados: Incluimos a 510 pacientes, distribuidas de la siguiente manera: 13.5% ($n = 69$) recibió una vacuna de vector viral, o bien la vacuna del vector adenovirus tipo 26 (Ad26.CoV2.S; Janssen; $n = 31$) o la vacuna del vector adenovirus de chimpancé (ChAdOx; AstraZeneca; $n = 38$). El 86.5% restante ($n = 441$) recibió una vacuna de ARN mensajero de Pfizer-BioNTech ($n = 336$) o Moderna ($n = 105$). La muestra de pacientes no expuestas fue de $n = 1190$. No se hallaron diferencias en ninguno de los parámetros evaluados ni en resultados reproductivos ni en resultados de FIV en pacientes vacunadas con vacunas de adenovirus ni ARN mensajero. Al comparar los resultados tras la vacunación con diferentes tipos de vacuna entre los grupos expuesto y no expuesto, se obtuvieron resultados similares en los días de estimulación y las dosis de hormona foliculo-estimulante administradas. Finalmente, los números de ovocitos fueron los siguientes: Johnson & Johnson ($9,2 \pm 2,6$), AstraZeneca ($7,7 \pm 1,2$), Moderna ($11,3 \pm 1,8$), Pfizer ($12,6 \pm 1,0$), and the unvaccinated group ($10,2 \pm 1,5$), $P = 0.057$.

Conclusión: Estos resultados tempranos sugieren que no hay un efecto deletéreo medible sobre los resultados reproductivos, independientemente del tipo de vacuna recibida.